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IN MONTANA EIGHTH JUDICIAL DISTRICT COURT
CASCADE COUNTY

ROSALIE MURPHY, Plaintiff, v. KB ORTHOPEDICS, INC., KARL BUHR, and John Does 1-10, Defendants.	Cause No: ADV-21-0157 Michele R. Levine COMPLAINT FOR DAMAGES and DEMAND FOR JURY TRIAL

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff, ROSALIE MURPHY ("PLAINTIFF") residing in Butte, Montana, by way of Complaint against KB ORTHOPEDICS, INC, and KARL BUHR (collectively referred to herein as "Distributor", "Distributor Defendants" and/or "Defendants"); states as follows:

SUMMARY OF PLAINTIFF'S ALLEGATIONS

1. This is a lawsuit involving defective metal on metal ("MoM") hip replacement components promoted, marketed, distributed, sold, serviced, and supported by Defendants.

2. The particular components at issue in this case were marketed by Defendants as the "DePuy Pinnacle MoM hip replacement system" (hereafter "DePuy Pinnacle" or "Pinnacle").

3. The Pinnacle Device was manufactured by Johnson & Johnson and its subsidiary DePuy Orthopaedics, Inc. (hereafter, collectively "Johnson & Johnson".) Johnson & Johnson also manufactured another MoM hip implant called the "ASR". Both devices were made with articulating surfaces made of the same or materially similar Cobalt Chrome alloy.

4. Defendants marketed the Pinnacle devices as having significant advantages over other hip devices and hip replacement systems.

5. Defendants marketed MoM hip implants, including the DePuy Pinnacle device, as having significant advantages over other, non-MoM hip replacement systems.

6. Despite Defendants' claims of advantage, both the Pinnacle and the ASR were defective and unreasonably dangerous for the same reason: the Cobalt Chrome articulating surfaces released toxic heavy metals leading to a high rate of injury as well as revision (replacement) surgery compared with non-MoM implants.

7. In fact, in 2010, Johnson & Johnson were forced to recall their ASR device because of a "higher than expected revision rate" in those devices. Defendants were aware of this recall and assisted in administering it.

8. Following the ASR Recall, and instead of warning of the similarities between the articulating surfaces of the ASR and Pinnacle implants and outcomes in both sets of patients, Defendants attempted to distinguish the Pinnacle from the ASR based upon factors that did not weigh on the actual clinical risks of the toxic heavy metal poisoning.

9. Defendants played an integral role in the omissions and misinformation that resulted in the orthopedic community and Plaintiff's surgeon, in particular, using the Pinnacle.

10. Pinnacle Devices release toxic heavy metals into hip implant recipients' tissue, system, and bloodstream.

11. Defendants are and were aware the metal released from Pinnacle Devices result in unreasonably high rates of negative clinical outcomes, including:

a. elevated levels of cobalt and chromium;
b. tissue death;
c. bone death;
d. loosening;
e. pseudotumors;
f. etc.

12. Defendants are and were aware that these negative clinical outcomes:

a. manifest in severe pain and limitations on mobility;
b. are progressive in nature such that the impact worsens with time and exposure;
c. represent an unreasonable risk of harm to patients;
d. result in a higher than expected rate of failure necessitating additional surgeries to replace failed implants;
e. lead to injuries which can persist even beyond the removal of the failed implants.

13. Plaintiff was implanted with the Pinnacle and has suffered substantial injuries and damages due to the defects and unreasonable danger associated with the device.

DEFENDANTS

14. KB ORTHOPEDICS, INC., at all times relevant to this complaint, was a Montana corporation with its citizenship and principal place of business at 620 High Park Way, Missoula, Montana 59806-4947.

15. Upon information and belief, KB ORTHOPEDICS, INC. was involuntarily dissolved, without publication of a notice of dissolution, in 2018. *See* MCA 35-14-1407.

16. KB ORTHOPEDICS, INC. is an active Idaho corporation organized under the laws of Montana.

17. From 2000 to present, KB ORTHOPEDICS, INC. was the exclusive distributor for the Johnson & Johnson's hip implants, including the DePuy Pinnacle and ASR, in Montana.

18. KB ORTHOPEDICS, INC. knew or should have known in-depth information regarding the DePuy Pinnacle product, including, without limitation, the purpose, design, intended use, marketing, surgical technique, risks, benefits, and product performance, among other things.

19. As the exclusive distributor for Montana, KB ORTHOPEDICS, INC. was a lucrative business that derived substantial amounts of money from commissions on sales and sales growth incentives within its assigned territory.

20. KARL BUHR, at all times relevant to this complaint, is and was a Montana citizen residing at 1008 26th Ave. SW Great Falls, MT 59404-36181.

21. From 2000 until present, KARL BUHR has had the exclusive contract with Johnson & Johnson and its subsidiaries through which he and his company KB ORTHOPEDICS, INC. served as the exclusive distributor for the DePuy Pinnacle in Montana

22. As such, KB ORTHOPEDICS, INC. and KARL BUHR, were responsible for informing & educating medical providers, marketing, selling, facilitating distribution of product to, servicing and supporting Plaintiff's orthopedic surgeons and the Pinnacle hip replacement at issue in this matter.

23. On information and belief, since 2000, Defendants contracted with Johnson & Johnson and its DePuy subordinates for the facilitation of distribution, sales, marketing to medical providers, informing & educating medical providers, servicing and support of DePuy Pinnacle hip replacements implanted in Montana patients, such as the Plaintiff in this matter.

24. Defendants were responsible for informing, educating, marketing, selling, facilitating distribution of product to, servicing and supporting Plaintiff's orthopedic surgeons regarding its product portfolio and, in particular, the Pinnacle hip replacement at issue in this matter.

25. Importantly, this knowledge was not simply the result of information provided by Johnson & Johnson. Instead, much of the knowledge Distributor Defendants gained and shared about hip implants, including the DePuy Pinnacle, was the result of independently gained knowledge and direct communication between the orthopedic community and Defendants.

26. To be clear, Defendants were not simply a mouthpiece for Johnson & Johnson. Defendants would attend conferences and workshops held by a variety of professionals and gain knowledge from sources independent of Johnson & Johnson. This knowledge was used by Distributor Defendants during their direct contacts with the orthopedic community, including with Plaintiff's surgeon.

27. Importantly, Defendants attended most—if not all—surgeries at which the products in their portfolio were implanted in the geographical region over which they were responsible. This gave Defendants knowledge regarding the performance of those products during surgery and instruments used to implant them, as well as interactions with those surgeons, which were independent from the information in Johnson & Johnson's possession.

28. Most importantly, Defendants and/or their sales representatives attended numerous surgeries in which an ASR or Pinnacle device was revised due to a metal reaction. This means that Defendants had direct and independent knowledge regarding failures of Johnson & Johnson's MoM implants, including the ASR and Pinnacle, which is at issue here. They were direct witness to failures caused by reactions to toxic heavy metals.

29. Defendants were required to inform Johnson & Johnson within 48 hours of each occasion where they came to know that an ASR or Pinnacle implant was revised.

30. This was part of Johnson & Johnson's requirement to perform post-market surveillance on their products.

31. Upon information and belief, Defendants failed to report to Johnson & Johnson regarding each such revision of which Defendants became aware.

32. This direct and independent knowledge regarding the failed MoM implants meant that Defendants knew or should have known that the Cobalt Chrome articulating surfaces, used in both the ASR and the Pinnacle, represented an unreasonable danger to patients and that the marketing materials provided to them by the Johnson & Johnson did not adequately inform the public and orthopedic community regarding these dangers.

33. In the course of executing their job duties, Defendants not only shared information sourced from Johnson & Johnson which Defendants knew or should have known was materially false, they *omitted* material information in their independent possession regarding the known dangers of the MoM implants which they sold, including the Pinnacle.

JURISDICTION AND VENUE

34. Jurisdiction is proper in the State Court of Montana because KARL BUHR is a citizen of the state of Montana, residing in Cascade County, Montana. Further both Defendants own property in Montana; conduct business in Montana; and engaged in conduct resulting in the accrual of a tort in Montana. Pursuant to §§ 25-2-122, and 30-14-133, MCA, venue properly lies in the Montana Eighth Judicial District.

THE PINNACLE DEVICE

35. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), and fracture among other degenerative conditions.

36. The hip joint connects the femur bone of a patient's leg to the patient's pelvis. The hip joint is like a ball in a socket. The socket portion of the hip is called acetabulum. The femoral head at the top of the femur bone rotates within the acetabulum.

37. The Pinnacle Device includes four components: 1) the metal femoral stem, which is inserted inside the femur bone, 2) the cobalt chrome metal alloy femoral head (or ball), which connects to the top of the stem and then makes contact with, 3) the liner, which is attached to the interior portion of the, 4) metal acetabular cup (socket). The acetabular cup, or socket, is comprised of a titanium metal alloy on its outer shell. Either a plastic, ceramic, or cobalt-chromium metal alloy liner is then placed on the inside of the acetabular cup. The metal femoral head articulates against the liner.

38. The cobalt-chrome metal alloy liner is branded as the "Ultamet" liner. The Pinnacle with an Ultamet liner is a "metal-on- metal" device because both articulating surfaces - the femoral head (ball) and acetabular liner (socket) - are made of cobalt-chromium metal. For the purposes of this complaint, reference to the Pinnacle device, generally, is a reference to the Pinnacle device where it is used with an Ultamet liner.

39. Defendants focused their marketing strategy to cater to younger and more active patients. For example, Mike "Coach K" Krzyewski, coach of the US Olympic Basketball team and the Duke University men's basketball team, was a celebrity spokesperson for the Pinnacle. Defendants disseminated marketing materials showing an active "Coach K" on a basketball court.

Other materials showed a hip implant recipient using an elliptical machine. Additional marketing materials claimed, "Imagine going for a bike ride, playing a doubles tennis match or just climbing the stairs. Thanks to DePuy Orthopaedics' hip replacements, more and more people are getting back to feeling like themselves and moving more naturally than they ever thought possible."

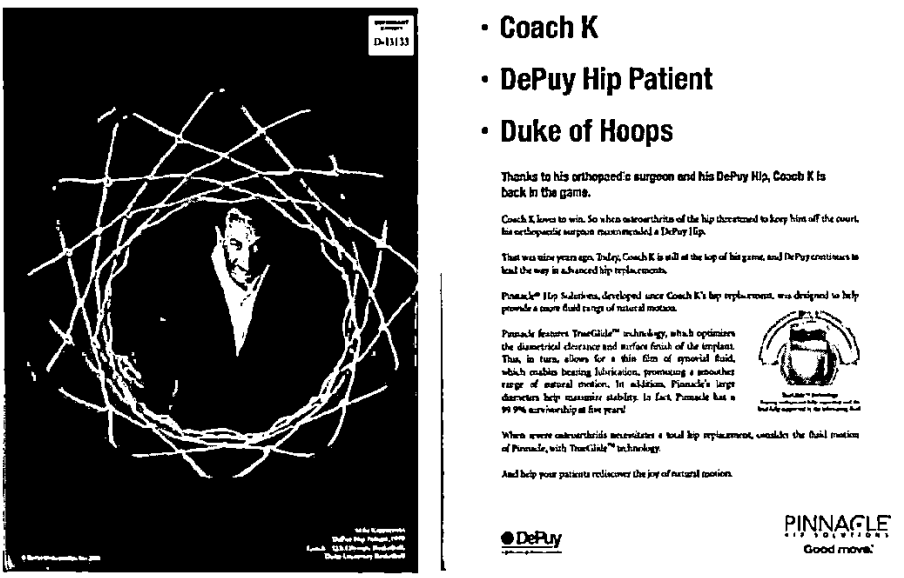
40. Additionally, defendants marketed the Pinnacle Device as

a. "uniquely designed to meet the demands of active patients like you" and disseminated advertisements with pictures of a young woman trying on hiking boots in an athletic shoe store;

b. a superior device featuring TruGlide technology, allowing the body to create a thin film of fluid lubrication between surfaces, which enables "a more fluid range of natural motion;"

c. the best surgical option that "recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

d. having "99.9% survivorship at five years!"



41. Defendants are and were aware that Pinnacle Devices had a higher than expected rate of failure and that survivorship with these devices did not reach 99.9% as they claimed.

42. The Pinnacle Device with an Ultamet liner is ultimately defective as it causes release of toxic heavy metals due to the articulation of two cobalt chrome metal alloy surfaces against each other.

43. This process is progressive, with greater metal release over time and increasing clinical reaction. Unfortunately, the toxic heavy metals result in severe injury to the hip joint as well as various systemic maladies.

44. This can include high metal levels, metallosis, pseudotumors, infection, loosening, tissue death, bone death, neurological issues, and many other problems which present with symptoms of pain and loss of function. If the implants are not removed early enough, the effects can be irreversible and permanent.

45. The FDA has received thousands of adverse event reports regarding problems associated with, or attributed to, the Pinnacle.

46. A number of governmental regulatory agencies have recognized the problems caused by metal-on-metal implants, including the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

47. Similarly, the Alaska Department of Health issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

48. Despite a recall of their other MoM device, the ASR, and knowledge that the Pinnacle represents a similar unreasonable risk of harm to patients, Defendants' continue to misrepresent the Pinnacle as a high-quality, safe and effective hip replacement product.

DEFENDANTS WERE CRITICAL TO THE PINNACLE OMISSION AND MISINFORMATION CAMPAIGN

49. Johnson & Johnson used local distributors to directly market their products to the medical community within each distributor's geographical region.

50. These distributors, including Defendants and their sales representatives, formed close relationships with their surgeons in order to gain the surgeons' trust regarding the distributors' and sales representatives' claims about the products.

51. In many situations, these distributors, including Defendants and their sales representatives, served as either the surgeons' primary or only source of information regarding Johnson & Johnson hip implants, including the Pinnacle and ASR.

52. Johnson & Johnson contracted with Defendants to hire, train, and supervise sales representative agents to educate the orthopedic community in Defendants' territory, including Plaintiff's orthopedic surgeon, regarding the claimed advantages of the Pinnacle hip replacement, answer any questions Plaintiff's orthopedic surgeon had regarding the products, assist Plaintiff's orthopedic surgeon at surgery regarding the products, sell the products to Plaintiff through Plaintiff's orthopedic surgeon agent, and service and support the Pinnacle hip replacement after the surgery.

53. Defendants and their sales representatives were required by Johnson & Johnson to undergo training regarding hip replacements generally and the Pinnacle Device specifically.

54. Defendants and their sales representatives served as the principal conduit by which surgeons receive information about the Pinnacle Device.

55. Defendants and their sales representatives were trained on how to promote the Pinnacle Device; this includes but is not limited to surgical instruments, surgical technique, product design, pre-surgical templating, component selection, risks, benefits, and sales strategies.

56. Defendants' sales representatives were trained on how to be of value in the operating room. Distributor Defendants' sales representatives were expected to be able to train their surgeons on how to use the surgical instruments to implant the Pinnacle and ASR.

57. In fact, their sales representatives were trained to be active participants in the surgeries to implant the products they sold. They would attend most, if not all, surgeries and be present in the operating room in order to assist the surgeons and surgical staff during each surgery.

58. The sales representatives were expected to assist surgeons in pre-op planning of both simple and complex surgical cases; identify competitive advantages within the DePuy product portfolio; demonstrate how to template, plan and consult on product options for primary and revision scenarios.

59. Defendants and their sales representatives were also trained on how to diminish and minimize surgeon concern regarding the ASR and Pinnacle implants. This was done in an effort to increase sales of these products despite valid safety concerns.

60. Defendants assisted in the 2010 recall of the ASR, particularly as it related to the medical community in their territory.

61. Thereafter, using both information provided to them by the Johnson & Johnson as well as information Defendants and their sales representatives independently gained through discussions with medical professionals, lectures, medical reports, and attendance at surgeries of failed MoM implants, Defendants unreasonably distinguished the Pinnacle from the ASR to medical professionals in their territory in an effort to continue to profit from the sale of Pinnacle implants.

DEFENDANTS WORKED DIRECTLY WITH PLAINTIFF'S SURGEON REGARDING PLAINTIFF'S SURGERY

62. Prior to Plaintiff's implant and revision surgeries, Defendants knew or should have known of the unreasonable dangers posed by the metal on metal Pinnacle hip replacement.

63. Defendants and their sales representatives were responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding the Pinnacle hip.

64. Prior to Plaintiff's surgery, Defendants and/or their sales representatives provided information to Plaintiff's orthopedic surgeon regarding the Pinnacle. This included information intended first to ensure Plaintiff's surgeon used the Pinnacle over any competitor's products.

65. Unfortunately, this meant that Defendants provided false information regarding the purported benefits of the Pinnacle as well as omitting critical information regarding its risks in an effort to profit from the sale of the implant.

66. In preparation for Plaintiff's implant surgery, Plaintiff's orthopedic surgeon contacted Defendants to notify them of the need for hip replacement components and instruments. Additionally, Defendants met with Plaintiff's orthopedic surgeon to template the surgery and confer with the surgeon regarding appropriate sizes, parts, instruments, and techniques.

67. Defendants' sales representative selected and provided the specific components and instruments to be available during the surgery and delivered them to the operating room where Plaintiff's surgery took place.

68. During Plaintiff's surgery, Defendants' sales representative was present in the operating room to provide the inventory of implant components as well as surgical instruments to use during implantation and any other assistance as requested by Plaintiff's surgeon and surgical staff.

69. At all times relevant to this Complaint, Plaintiff's orthopedic surgeon, nurses and hospital staff relied on information and assistance from Defendants and their sales representatives.

70. The above communications and information were provided to Plaintiff's orthopedic surgeon with the intended purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the metal on metal Pinnacle hip replacement instead of one of the competing hip replacements.

71. Defendants and their sales representatives' communications to the orthopedic community, including Plaintiff's surgeon, were in no way limited to the information provided on the Pinnacle hip packaging or labeling.

PLAINTIFF SUFFERED INJURIES AS A RESULT OF THE PINNACLE

72. At all times relevant to this Complaint, Plaintiff, is and was a citizen of the State of Montana.

73. Plaintiff suffered a displaced left hip fracture and underwent a left hip hemi-arthroplasty in 2007.

74. Plaintiff was implanted with the metal on metal Pinnacle hip replacement in September 2009, in Bozeman, Montana.

75. Over the ensuing years, Plaintiff unknowingly suffered heavy metal poisoning from the toxic heavy metals released by the hip replacement, resulting in injury and requiring surgery to remove the defective hip replacement.

76. On October 18, 2019, Plaintiff was forced to undergo surgical removal of the defective Pinnacle hip replacement due to toxic heavy metal poisoning.

77. Plaintiff continues to undergo the slow process of recovery from the surgery that would not have been necessary but for the defective nature of the Pinnacle hip replacement.

78. As a direct and proximate result of the defective Pinnacle hip replacement, Plaintiff was required to undergo surgical removal of the defective device, now has a hip replacement with decreased longevity, and suffered injuries, including but not limited to significant pain, permanent tissue destruction, permanent muscle destruction, bone destruction, metal wear, removal of a pseudotumor, and toxic heavy metal poisoning.

79. Plaintiff expects to continue suffering such injuries in the future as a result of the injuries received from the Pinnacle.

80. As a direct and proximate result of the defective Pinnacle, Plaintiff incurred medical expenses and expects to incur additional medical expenses in the future.

81. As a direct and proximate result of the defective Pinnacle, Plaintiff incurred lost earning potential, income, and earnings.

82. As a direct and proximate result of the defective Pinnacle, Plaintiff experienced emotional trauma and distress and is likely to experience emotional trauma and distress in the future.

83. Defendants knew or should have known that their conduct complained of herein, would harm Plaintiff. Defendants proceeded to act with intentional disregard for the high likelihood of injury to Plaintiff and others like her. Defendants acted with malice as that term is defined in Montana punitive damages law, and punitive damages are warranted in this case.

COUNT ONE - STRICT PRODUCT LIABILITY AND FAILURE TO WARN

84. All allegations asserted in this Complaint are incorporated by reference as if fully stated herein.

85. At all times relevant to this action, Defendants engaged in the business of selling, marketing, promoting, and placing into the stream of commerce the Pinnacle hip system.

86. The Pinnacle reached Plaintiff without substantial change in the condition in which it was designed, developed, promoted, manufactured, and sold.

87. At the time and on the occasions in question, the Pinnacle was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

88. At the time that Defendants, promoted, marketed, and sold the Pinnacle, such device contained defects that made it unreasonably dangerous and more dangerous than an average consumer would expect.

89. The foreseeable risk of harm from the defects in the Pinnacle hip system could

have been reduced or avoided by providing adequate instructions or warnings.

90. Defendants had sufficient notice about specific dangers associated with the Pinnacle hip system.

91. Defendants failed and continue to fail to provide adequate instructions or warnings regarding the defects in the Pinnacle hip system which were known by Defendants or should have been known by Defendants and could have been provided.

92. The Pinnacle was defective and unreasonably dangerous in that the labeling was insufficient to warn users of the hazardous conditions posed by said items, including but not limited to its propensity to cause permanent tissue and muscle death associated to release of heavy metal ions.

93. The Pinnacle was defective due to inadequate, or the absence of, warnings or instructions, including warning stickers, placards, or proper documentation to alert users regarding the hazards posed by the Pinnacle.

94. Defendants had duty to warn, including a continuing post-sale duty to warn, regarding the unreasonable risk of harm associated with the Pinnacle, particularly due to the progressive nature of the risk of the toxic heavy metal poisoning.

95. Defendants failed to exercise reasonable care to inform Plaintiff, Plaintiff's doctors, and the medical community about dangers regarding the Pinnacle.

96. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the Pinnacle, Plaintiff suffered the injuries described in paragraphs 72-83 above.

COUNT TWO - BREACH OF EXPRESS AND IMPLIED WARRANTIES

97. All allegations asserted in this Complaint are incorporated by reference as if fully stated herein.

98. Defendants sold and Plaintiff purchased the products at issue in this Complaint.

99. At all times relevant to this complaint, Plaintiff was in privity with Defendants.

100. Defendants expressly warranted that the Pinnacle was reasonably fit for its intended purpose as a hip replacement system. These warranties included, without limitation, the allegations above (*see* ¶¶ 4-5, 40-41, and 64-65) as well as the following:

a. The Pinnacle produced less wear than competing devices;
b. The Pinnacle bearing surfaces were all carefully tested;
c. The Pinnacle was a clinically safe system;
d. The Pinnacle did not exhibit high rates of revisions;
e. Fluid film lubrication would prevent contact of the ball and cup during articulation.

101. The representations set forth above contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform the affirmations of facts or promises.

102. Plaintiff was a reasonably foreseeable user of the Pinnacle.

103. Such representations by Defendants were meant to induce Plaintiff, through Plaintiff's physician, to purchase the products at issue in this Complaint.

104. Defendants' sale and distribution of the Pinnacle to Plaintiff and her physicians was also accompanied by implied warranties. The implied warranties include the warranty of fitness for a particular purpose, and the implied warranty of merchantability.

105. The products at issue in this Complaint did not conform to the warranties and representations made by Defendants.

106. Defendants breached the express warranties it provided with the products at issue in this Complaint.

107. As a direct and proximate result of the breach of the warranties regarding the Pinnacle, Plaintiff suffered the injuries as described in paragraphs 72-83 above.

COUNT THREE - FRAUD

108. All allegations asserted in this Complaint are incorporated by reference as if fully stated herein.

109. As stated above, Defendants made misrepresentations of material facts about the Pinnacle or intentionally concealed information about the Pinnacle from Plaintiff, Plaintiff's orthopedic surgeons, and the medical community prior to and after Plaintiff was implanted with the Pinnacle.

110. Defendants possessed (and possess) superior knowledge about the level of clinical testing and safety of the Pinnacle hip replacement, including the lack of reliable support for representations about the asserted clinical safety and failure rates of the metal on metal Pinnacle hip replacement.

111. Defendants were at all times relevant acting within the scope of their business for their own economic and pecuniary gains.

112. The Plaintiff and his surgeon were not able to discover Defendant's superior and specialized knowledge and experience about metal on metal Pinnacle product complaints, failures and revisions, and their systems for reporting and analyzing the same.

113. Defendants have failed in their duty to disclose known material facts to the Plaintiff and Plaintiff's surgeon regarding the Pinnacle, including but not limited to:

a. Falsely representing the Pinnacle had resolved the metal ion wear problems that had plagued similar metal-on-metal hip products, including the predicate systems on which it

was based, particularly after the 2010 recall of the DePuy ASR.

b. Falsely representing the Pinnacle as reducing wear and providing higher function for patients than other available hip systems.

c. Falsely representing the Pinnacle metal-on-metal bearing system as a lifetime hip product.

d. Falsely representing that the Pinnacle is a safer and stronger alternative when compared with other available hip systems, notwithstanding internal information dating as far back to 1995 to the contrary.

e. Falsely representing that the Pinnacle provided fluid film lubrication.

f. Failing to disclose the clinical significance and safety concerns regarding heavy metal poisoning, notwithstanding notice as early as 2006 from surgeons seeing increased revision rates with the Pinnacle device.

g. Failing to disclose patterns and trends of failure Pinnacle implants. *See also* ¶¶ 4-12, 29-33, and 39-48.

114. The above representations and omissions were material and were made with the intent to persuade and induce Plaintiff, Plaintiff's surgeon, and the medical community to choose and to fail to properly follow-up, with patients, such as and including Plaintiff, regarding the Pinnacle hip replacement system.

115. Defendants made the above representations or omissions knowing the misrepresentations were false or were ignorant of the truth of the assertions.

116. The above representations and omissions are reflected in Defendants' marketing of the Pinnacle product in Montana. Defendants directed the aggressive promotion of the Pinnacle products to Montana's orthopedic community through regular conversations, meetings, written publications, brochures, and field communications which reflect the representations and omissions detailed above. Through this marketing effort, Defendants established acceptance of their representations about the Pinnacle product's safety among surgeons in Montana's orthopedic community.

117. Defendants made the above misrepresentations or omissions with the intention and knowledge that their efforts would influence Montana surgeons and consumers in their decisions to select the Pinnacle hip replacement for surgical implantation in patients.

118. Plaintiff and Plaintiff's orthopedic surgeon justifiably relied upon and were induced to act in reliance on Defendants' misrepresentations or omissions and in fact purchased the Pinnacle based on these misrepresentations or omissions.

119. As a direct and proximate result of the breach of the warranties regarding the Pinnacle, Plaintiff suffered injuries as described in paragraphs 72-83 above.

COUNT FOUR - NEGLIGENCE

120. All allegations asserted in this Complaint are incorporated by reference as if fully stated herein.

121. The Defendants marketed, promoted, advertised, sold, distributed, serviced, and supported the Pinnacle for implantation into the bodies of consumers such as and including Plaintiff.

122. Sales representatives working for the Defendants were responsible for educating and continuously guiding surgeons regarding the proper patient selection, surgical planning, component selection, surgical technique, and post-surgery follow-up.

123. Surgeons, such as Plaintiff's surgeons, reasonably relied upon Defendants to properly perform these functions and Defendants had a duty to perform such functions and to protect Plaintiff from injury.

124. Defendants failed to properly perform these functions as described above, thereby breaching their duty to protect Plaintiff from injury.

125. Plaintiff suffered actual injury and loss because of said breach.

126. Defendants' failure to discharge these duties were a direct and proximate cause of Plaintiff's injuries as described in paragraphs 72-83 above.

COUNT FIVE - MONTANA CONSUMER PROTECTION ACT
[Pursuant to MCA § 13-14-101 *et. seq.*]

127. All allegations asserted in this Complaint are incorporated by reference as if fully stated herein.

128. Plaintiff is a consumer pursuant to § 30-14-102, MCA, because she purchased the Pinnacle and the services necessary for its implementation.

129. Defendants participated in trade and/or commerce in the distribution, marketing, selling, and servicing of the Pinnacle.

130. The acts by Defendants in this cause of action include, but are not limited to, the following deceptive and unfair acts:

a. Representing the Pinnacle as a device clinically proven to be safe and effective, while knowing those claims were false and without sufficient medical support.
b. Representing the Pinnacle to be of a higher quality and more desirable product than other available alternatives.
c. Failing to disclose adequate information about the safety and efficacy of the Pinnacle either before or after Plaintiffs' purchase.
d. Knowingly providing inadequate warnings about the Pinnacle's dangerous propensities.
e. Knowingly producing and publishing deceptive and misleading statements and advertisements regarding the safety of Pinnacle hips, while knowing of the defects and dangers associated to Pinnacle hips.
f. Doing all of the above with the sole intent of selling more Pinnacle hips and creating demand for Pinnacle hips by using deceptive or untrue statements of fact about the safety and benefits of Pinnacle hips.
g. *See also* ¶¶ 4-12, 29-33, and 39-48.

131. The actions of the Defendants discussed above amount to deceptive acts and trade practices. Such deceptive acts and trade practices breach the duty of fair trade and commerce Defendants owe to Plaintiff.

132. As the result of Defendants' breach of their duties of fair trade and commerce, Plaintiff has suffered damages and personal injuries as set forth in this Complaint.

133. Plaintiff seeks to recover their actual damages, treble damages, and attorneys'

fees from the Defendants pursuant to the provisions of the Montana Consumer Protection Act, specifically § 30-14-133, MCA.

DEMAND FOR JURY TRIAL

134. Plaintiff demands a 12-person jury trial on issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, prays for relief and judgment against Defendants as follows:

(a) For all damages to be proved at the time of trial;

(b) For punitive damages;

(c) For a reasonable sum of money to compensate Plaintiff for her attorney fees and costs incurred incident to the prosecution of the claim pursuant to any applicable law; and

(d) The award of any other relief, including treble damages, pre-judgment and post-judgment interest, to which Plaintiff may be entitled at law or in equity.

RESPECTFULLY SUBMITTED, this 9th day of March, 2021.

WESTERN JUSTICE ASSOCIATES, PLLC

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